Docket No.: 22114-00001-US1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Jerome Asius et al.

Application No.: 10/809,349 | Confirmation No.: 7560

Filed: March 26, 2004 | Art Unit: 3738

For: IMPLANT FOR SUBCUTANEOUS OR INTRADERMAL INJECTION | Examiner: P. B. Prebilic

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 41.37(a), this brief is filed within two months of the Notice of Appeal filed in this case on December 28, 2007, and is in furtherance of said Notice of Appeal.

The fees required under § 41.20(b)(2) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205.2:

Appendix B Evidence
Appendix C Related Proceedings

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is:

Aventis Pharmaceuticals Inc. , a Sanofi Aventis Company.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 21 claims pending in application.

B. Current Status of Claims

1. Claims canceled: 1-9
2. Claims withdrawn from consideration but not canceled: 20-22 and 28-30
3. Claims pending: 10-30
4. Claims allowed: 0
5. Claims rejected: 10-19 and 23-27

C. Claims On Appeal

The claims on appeal are claims 10-19 and 23-27

IV. STATUS OF AMENDMENTS

Applicant did not file an Amendment to the Claims After Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

As recited in independent claim 10, the present invention relates to a reconstitutable product, which upon the addition of water becomes a bioresorbable, injectable implant product (see, for example, page 5, lines 11-13 and page 9, line 39-page 10, line 1 of the original disclosure). The reconstitutable product comprises a freeze-dried composition (see, for example, page 5, lines 6-13 and page 9, line 36 of the original disclosure) of:

microparticles of at least one polymer of non-animal origin selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers (see, for example, page 3, lines 2-15 and page 5, lines 13-15 of the original disclosure); and

a hydrogel precursor consisting essentially of materials of non-animal origin, wherein said precursor forms a hydrogel upon the addition of water (see, for example, page 4, lines 21-28 and page 5, lines 13-15 of the original disclosure).

According to claim 11, the microparticles are bioresorbable within a period of about 1 year to about 3 years (see, for example, page 2, lines 33-35 of the original disclosure).

According to claim 12, the microparticles consist of a polymer selected from the group consisting of poly-L-lactic acid, poly-D-lactic acid, and mixtures thereof (see, for example, page 3, lines 23-25 of the original disclosure).

According to claim 13, the materials of the hydrogel precursor comprise a gelling agent, and a cryoprotecting agent (see, for example, page 6, lines 5-7 of the original disclosure).

According to claim 14, the gelling agent is a cellulose derivative (see, for example, page 4, line 28 of the original disclosure).

According to claim 15, the cellulose derivative is at least one member selected from the group consisting of carboxymethylcellulose and hydroxypropylmethylcellulose (see, for example, page 4, lines 29-32 of the original disclosure).

According to claim 16, the gelling agent is synthetic hyaluronic acid (see, for example, page 4, line 34 of the original disclosure).

According to claim 17, the cryoprotecting agent is apyrogenic mannitol (see, for example, page 6, line 7 of the original disclosure).

According to claim 18, the reconstitutable product further comprises a surfactant (see, for example, page 4, line 37 to page 5, line 5 and page 6, line 8 of the original disclosure).

According to claim 19, the surfactant is at least one member selected from the group consisting of polyoxyethylene sorbitan monooleate and polyoxypropylene block copolymer surfactant (see, for example, page 4, line 37 to page 5, line 5 of the original disclosure).

According to independent claim 23, the invention relates to a reconstitutable bioresorbable injectable implant product made by freeze-drying a composition consisting essentially of (see, for example, page 5, lines 11-13 and page 9, line 39-page 10, line 1 of the original disclosure):

bioresorbable microspheres or microparticles suspended in a gel, said gel consisting essentially of materials of non-animal origin (see, for example, page 3, lines 2-9 and page 5, lines 13-15 of the original disclosure),

said microspheres or microparticles consisting of at least one polymer of non-animal origin selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers (see, for example, page 3, lines 2-15 and page 5, lines 13-15 of the original disclosure).

Claim 24 further recites a kit that comprises the reconstitutable product of claim 10 in a vial (see, for example, page 5, line 9 of the original disclosure).

According to claim 25, the kit further comprises a container of water for injection (see, for example, page 5, lines 10-13 of the original disclosure).

According to claim 26, the kit further comprises a syringe (see, for example, page 5, lines 6-11 of the original disclosure).

Independent claim 27 is concerned with a kit comprising a syringe prefilled with a bioresorbable injectable implant for human administration consisting essentially of (see, for example, page 5, lines 6-7 of the original disclosure):

bioresorbable microspheres or microparticles suspended in a gel, said gel consisting essentially of materials of non-animal origin, said microspheres or microparticles consisting of at least one polymer of non-animal origin selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers (see, for example, page 3, lines 2-15 and page 5, lines 13-15 of the original disclosure).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Has the Examiner established that Claims 10-19 and 23 are obvious and therefore unpatentable under 35 USC 103(a) over the cited art and namely over US Patent 5,356,629 to Sander et al. in view of US Patent 5,470,582 to Supersaxo et al. as stated in the Final Office Action dated August 28, 2007?

B. Has the Examiner established that Claims 24-27 are obvious and therefore unpatentable under 35 USC 103(a) over the cited art and namely over US Patent 5,356,629 to Sander and US Patent 5,470,582 to Supersaxo and further in view of US Patent 5,599,852 to Scopelianos et al. as stated in the Final Office Action dated August 28, 2007?

VII. ARGUMENT

A. Sander et al and Supersaxo et al. fail to render obvious claims 10-19 and 23

Claims 10-19 and 23 were rejected under 35 USC 103(a) as being unpatentable over US Patent 5,356,629 to Sander et al.(hereinafter also referred to as "Sander") in view of US Patent 5,470,582 to Supersaxo et al. (hereinafter also referred to as "Supersaxo"). The cited references do not render obvious claims 10-19 and 23.

Sander relates to moldable implants. The examples of Sander refer to the moldable compositions as **putties**. One of ordinary skill in the art understands the definition of "gel," and would never consider a "putty" composition to fall within that definition. A gel is typically defined as "a colloid in which the disperse phase has combined with the continuous phase to produce a jelly-like product." See Hawley's Condensed Chemical Dictionary, *555*, 12th Ed., 1993(Enclosed as Exhibit I). In fact, a reason for allowance in applicant's parent application 09/242,103, now US Patent 6,716,251 was that the art related to a putty and not a gel. The issue in that application was similar to that in the present application even though a different reference, i.e. US Patent 5,597,897 to Ron, was being applied as the primary reference. (US Patent 5,356,629 to Sander, the primary reference applied in this application, was considered in the parent case and was applied as a secondary reference in a rejection on page 8 (Enclosed as Exhibit II) in an office action dated October 30, 2002.)

In the parent application 09/242,103, now US Patent 6,716,251, the Examiner stated on pages 2 and 3(Enclosed as Exhibit III) of the Notice of Allowability dated May 21, 2003 under Reasons for Allowance:

"----Appellant argued that the material of Ron (US 5,597,897) does not constitute a gel as defined by Hawley's Condensed Chemical Dictionary. Appellant defined gel as "a colloid in which a disperse phase has combined with the continuous phase to produce a jelly-like product." The examiner asserts that the Appellant has estopped himself from any other definition by this argument. Therefore, since Ron does not clearly disclose that the mixture has all the properties of a gel as set forth in Appellant's definition thereof, the Examiner posits that Ron fails to anticipate or render obvious the present claims."

The importance of the claim recitation "gel" was further confirmed in the Reexamination 90/007,252 of parent US Patent 6,716,251 at page 2 (Enclosed as Exhibit IV)under the Statement of Reasons for Patentability and/or Confirmation as follows:

"Further a 'gel' is seperately defined as a jellylike substance formed by cooling a colloidal solution into a solid" (see Webster's New World Dictionary, Third Edition)."

The malleable putties of Sander are not inherently gels and even more remote are not hydrogels as explicitly recited in claim 10 and claims dependent thereon.

Sander does not even remotely suggest a product that is reconstitutable, which upon the addition of water becomes a bioresorbable, injectable implant product that is a hydrogel.

In addition, Sander does not require employing microparticles as recited in the present claims. If anything, Sander teaches away from selecting microparticles of the biocompatible particles since the preferred biocompatible particles have an average particle size of about 0.1 to about 3 mm (see column 4, line 34). Moreover, Sander has failed to attach any importance to the particle size of the biocompatible material since the examples do not even remotely refer to the particle sizes of the biocompatible material.

It should also be noted that the polymers of the microparticles recited in the present claims are merely a small group of the numerous possible polymers contemplated by Sander.

In addition, the cellulose derivatives that can be employed according to the present invention act as gelling agents upon the addition of water. On the other hand, the cellulose derivatives that can be employed in Sander are to function as the matrix in which the biocompatible material is to be dispersed and **not as a gelling agent**.

The above differences between the present claims and Sander are important in view of the vastly different uses intended and the distinct properties needed for these uses. In particular, Sander is concerned with an implant into a bone defect site. The material of Sander after being implanted is to be shaped such as with a spatula and once it is dried it will harden. On the other hand the claimed products after being reconstituted are to be injected to fill up wrinkles, thin lines, skin cracks and scars, for reparative or plastic surgery, aesthetic dermatology, and for filling up gums in dental treatment. Accordingly having a material that hardens as a bone graft such as Sander would be detrimental for the uses intended for the products of the present invention upon being reconstituted. Such reconstituted materials should remain flexible and soft like skin not hard like bone.

Supersaxo does not overcome the above discussed deficiencies of Sander with respect to rendering obvious claims 10-19 and 23. Supersaxo was relied upon for a disclosure of freeze drying in order to stabilize the materials for storage. Accordingly, even if Supersaxo were combined with Sander, the present invention would still not be suggested. In particular, even if materials of Sander, were freeze dried, such materials would not be reconstitutable, which upon the addition of water become bioresorbable, injectable implant products that are **gels**, according to the present claims or **hydrogels**. To be reconstituable to a gel or more especially to a hydrogel, the composition that is freeze dried would need to be in the from of a gel prior to the freeze drying. As discussed above, the products of Sander are **not gels**.

B. Sander et al and Supersaxo et al. and Scopelianos et al. fail to render obvious claims 24-27

Claims 24-27 were rejected under 35 USC 103(a) as being unpatentable over Sander and Supersaxo and further in view of US Patent 5,599,852 to Scopelianos et al. The cited references do not render obvious claims 24-27. Scopelianos et al do not overcome the above discussed deficiencies of Sander and Supersaxo with respect to rendering obvious claims 10-19 and 23. Scopelianos et al were merely relied upon for a disclosure of including a kit with a syringe. Accordingly, claims 24-27 are patentable for at least those reasons as to why claim 10 is patentable.

Discussion of Case Law

Furthermore, the cited art lacks the necessary direction or incentive to those of ordinary skill in the art to render a rejection under 35 USC 103 sustainable. The cited art fails to provide the degree of predictability of success of achieving the properties attained by the present invention needed to have a rejection under 35 U.S.C. 103 sustained. See *KSR Int'l Co. v. Teleflex*, 127 S. Ct. 1727 (2007), *Diversitech Corp. v. Century Steps, Inc.*, 7 USPQ2d 1315 (Fed. Cir. 1988), *In re Mercier*, 187 USPQ 774 (CCPA 1975) and *In re Naylor*, 152 USPQ 106 (CCPA 1966).

Moreover, the properties of the subject matter and improvements which are inherent in the claimed subject matter and disclosed in the specification are to be considered when evaluating the question of obviousness under 35 USC 103. See *KSR Int'l Co. v. Teleflex,, supra, Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923 (Fed. Cir. 1990), *In re Antonie*, 195 USPQ 6 (CCPA 1977), *In re Estes*, 164 USPQ 519 (CCPA 1970), and *In re Papesch*, 137 USPQ 43 (CCPA 1963).

No property can be ignored in determining patentability and comparing the claimed invention to the prior art. Along these lines, see *In re Papesch*, supra, *In re Burt et al*, 148 USPQ 548 (CCPA 1966), *In re Ward*, 141 USPQ 227 (CCPA 1964), and *In re Cescon*, 177 USPQ 264 (CCPA 1973).

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A. As indicated above, the claims in Appendix A include the amendments filed by Applicant on June 15, 2007.

Please charge any fees due with this paper to our Deposit Account No. 22-0185, under Order No. 22114-00001-US1 from which the undersigned is authorized to draw.

Dated: February 27, 2008

Respectfully submitted,

Electronic signature: /Burton A. Amernick/
Burton A. Amernick
Registration No.: 24,852
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street
Suite 1100
Washington, DC 20006
(202) 331-7111
(Fax)(202)-293-6229
Attorney for Applicant

APPENDIX A-CLAIMS INVOLVED IN APPEAL

Claims Involved in the Appeal of Application Serial No. 10/809,349

10. A reconstitutable product , which upon the addition of water becomes a bioresorbable, injectable implant product, wherein said reconstitutable product comprises a freeze-dried composition of:

microparticles of at least one polymer of non-animal origin selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers; and

a hydrogel precursor consisting essentially of materials of non-animal origin, wherein said precursor forms a hydrogel upon the addition of water.

11. The reconstitutable product according to claim 10 wherein said microparticles are bioresorbable within a period of about 1 year to about 3 years.

12. The reconstitutable product according to claim 10 wherein said microparticles consist of a polymer selected from the group consisting of poly-L-lactic acid, poly-D-lactic acid, and mixtures thereof.

13. The reconstitutable product according to claim 10 wherein the materials of said hydrogel precursor comprise:

a gelling agent, and

a cryoprotecting agent.

14. The reconstitutable product according to claim 13 wherein said gelling agent is a cellulose derivative.

15. The reconstitutable product according to claim 14, wherein said cellulose derivative is at least one member selected from the group consisting of carboxymethylcellulose and hydroxypropylmethylcellulose.

16. The reconstitutable product according to claim 13, wherein said gelling agent is synthetic hyaluronic acid.

17. The reconstitutable product according to claim 13, wherein said cryoprotecting agent is apyrogenic mannitol.

18. The reconstitutable product according to claim 10 further comprising a surfactant.

19. The reconstitutable product according to claim 18, wherein said surfactant is at least one member selected from the group consisting of polyoxyethylene sorbitan monooleate and polyoxypropylene block copolymer surfactant.

23. A reconstitutable bioresorbable injectable implant product made by freeze-drying a composition consisting essentially of:

bioresorbable microspheres or microparticles suspended in a gel, said gel consisting essentially of materials of non-animal origin,

said microspheres or microparticles consisting of at least one polymer of non-animal origin selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers.

24. A kit comprising the reconstitutable product of claim 10 in a vial.

25. The kit of claim 24 further comprising a container of water for injection.

26. The kit of claim 24 further comprising a syringe.

27. A kit comprising a syringe prefilled with a bioresorbable injectable implant for human administration consisting essentially of:

bioresorbable microspheres or microparticles suspended in a gel, said gel consisting essentially of materials of non-animal origin, said microspheres or microparticles consisting of at least one polymer of non-animal origin selected from the group consisting of lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid co-polymers.

APPENDIX B-EVIDENCE

A copy of evidence pursuant to §§ 1.130, 1.131, or 1.132 and/or evidence entered by or relied upon by the examiner that is relevant to this appeal is attached hereto.

Exhibit I.-Hawley's Condensed Chemical Dictionary *555* (12th Ed. 1993).- Filed along with Response dated June 15, 2007 and entered into the record by the Examiner in the office action dated August 28, 2007.

Exhibit II.-Page 8 office action dated October 30, 2002 in parent application 09/242,103, now US Patent 6,716,251.- Filed along with Response dated December 7, 2007and entered into the record by the Examiner in the Advisory Action dated December 18, 2007.

Exhibit III.-Notice of Allowability dated May 21, 2003 in parent application 09/242,103, now US Patent 6,716,251- Filed along with Response dated December 7, 2007and entered into the record by the Examiner in the Advisory Action dated December 18, 2007.

Exhibit IV.-Reexamination 90/007,252 of parent US Patent 6,716,251 at page 2 under the Statement of Reasons for Patentability and/or Confirmation- Filed along with Response dated December 7, 2007and entered into the record by the Examiner in the Advisory Action dated December 18, 2007.

APPENDIX C-RELATED PROCEEDINGS

No related proceedings are referenced in II. above, hence copies of decisions in related proceedings are not provided.